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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,401	07/31/2001	Shoshana Merchav	01/22310	1613

7590 01/17/2003

G E Ehrlich  
Suite 207  
2001 Jefferson Davis Highway  
Arlington, VA 22202

EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 01/17/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/890401

Applicant(s)

Morchew et al

Examiner

Haff

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10/30/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-99 is/are pending in the application.
- Of the above claim(s) 21-50 + 71-99 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-20 + 51-70 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3+4 (filed 3/13 + 3/22/02)
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

In a response of 10/30/02, applicants elected Group I claims 1-20 and 51-70 without traverse.

Claims 21-50 and 71-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7 (filed 10/30/02).

Claims examined on the merits are 1-20 and 51-70.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

10 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 and 51-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 2 of claim 1 and where recited in other claims, "progenitor cells" is uncertain as to meaning and scope. The difference between progenitor cells and hemopoietic stem cells is uncertain, and it is uncertain as to cells that are progenitor cells and cells that are not progenitor cells. If progenitor cells are any cells capable of transformation into other cells, then the independent claims should require only undifferentiated progenitor cells, and in a dependent claim further define the progenitor cells as undifferentiated hemopoietic stem cells.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 15 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 and 51-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al (5,541,107) in view of Sussman et al (5,266,476) and Stephanopoulos et al (5,510,262).

25 Claims 1-20 are drawn to a method of expanding/maintaining undifferentiated hemopoietic stem cells or progenitor cells by seeding the cells into a stationary phase plug-flow bioreactor in which a three-dimensional stromal cell culture has been pre-established on a non-woven fibrous matrix in the form of a sheet, and expanding/maintaining the stem cells or progenitor cells.

Claims 51-70 require a method of transplanting undifferentiated hemopoietic stem cells or progenitor cells resulting from expanding/maintaining the cells by the method of claims 1-20.

Naughton et al disclose growing stromal cells on a three-dimensional matrix which can be formed from a polymeric material to produce a three-dimensional stromal matrix (col 9, lines 16-20 and 49-51 and col 13, lines 8-14), inoculating the stromal matrix with stem cells (col 15, lines 41 and 57 and col 21, lines 3, 9, and 26) such as hematopoietic stem cells (col 21, line 3), maintaining the stem cells on the matrix *in vitro* where proliferation of the cells is maximized (col 21, lines 2-3), and implanting the stem cells *in vivo* to repopulate bone marrow (col 16, lines 58-67 and col 21, lines 4-5).

Sussman et al disclose a fibrous matrix for cell cultivation. The matrix can be a non-woven fiber sheet (col 4, line 56), and can have a pore volume of 40-90%, a pore size of 10-100  $\mu\text{m}$ , a height of 50-500  $\mu\text{m}$ , and a fiber diameter of 0.5-50  $\mu\text{m}$  (col 2, lines 47-65). Matrix sheets can be used as a packing in a column (paragraph bridging cols 7 and 8), and the matrix can be coated with poly-D-lysine (col 13, line 68).

Stephanopoulos et al disclose a cell-culturing reactor having an inlet and outlet for culture medium and containing a macroporous support between the inlet and outlet having pores of a size that allows cells to collect within the pores and oxygen and nutrients to migrate into the pores for consumption by the cells (paragraph bridging cols 2 and 3).

It would have been obvious to use as the matrix of Naughton et al the non-woven fibrous sheet packed in a column for cell culture disclosed

by Sussman et al to obtain a flow through reactor having an inlet and outlet as suggested by Sussman et al and Stephanopoulos et al since such a reactor would have been expected to provide advantages of a beneficial environment for cell culture and continuous flow.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

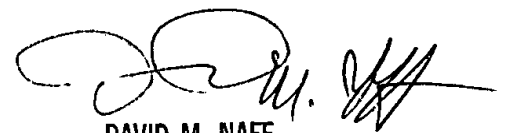
10 If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

15 The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 12857

DMN

25 1/15/03